

REMARKS

I. **The Amendments**

Following entry of this Amendment, claims 1-20 are pending in this application.

The specification was amended to correct typographical errors. No new matter has been added.

Claim 12 was amended to clarify the element "the function" to read "the supporting function". No new matter has been added. Applicant respectfully submits that claims 1-20 are in condition for immediate allowance. Applicant addresses the Examiner's rejections in the order they were presented in the Office Action.

II. **Election of Species**

Applicant affirms the election of species as requested by the Examiner.

III. **35 U.S.C. §112, second paragraph**

a. Claims 1-15 were rejected under 35 U.S.C. § 112, second paragraph, for being indefinite. According to the Examiner, claims 1-15 are allegedly incomplete with respect to the delivery of a molecule. Applicant respectfully traverses the rejection. The claims recite "administering amniotic epithelial cells to the skin of the patient" and that "said cells are capable of delivering said molecule." A skilled artisan would appreciate the delivery of the molecule as described in the claims and the claims are therefore definite.

Applicant respectfully requests withdrawal of this rejection.

b. Claims 9 and 16-20 were rejected under 35 U.S.C. § 112, second paragraph, for being indefinite. According to the Examiner, claims 9 and 16-20 are allegedly indefinite for reciting the term "a nutrient-poor environment found on the skin". Applicant respectfully traverses the rejection.

One of skill in the art would understand the term, especially in the context of the subject invention. For example, the claims recite the "environment found on the skin" and further describe it as "nutrient-poor". A skilled artisan would understand the term

as it relates to the skin and Applicant respectfully submits that the subject claims are sufficiently definite.

Applicant respectfully requests withdrawal of this rejection.

c. Claims 12 and 13 were rejected under 35 U.S.C. § 112, second paragraph, for being indefinite. According to the Examiner, claims 12 and 13 are allegedly indefinite for reciting the term "the function" without further antecedent. The term appears in claim 12 and claim 13, which depends from claim 12. Claim 12 has been amended to clarify that the function referred to is the "supporting function." Applicant respectfully submits that claims 12 and 13 are sufficiently definite.

Applicant respectfully requests withdrawal of this rejection.

IV. 35 U.S.C. §112, first paragraph

Claims 1-20 were rejected under 35 U.S.C. § 112, first paragraph, for being non-enabling. According to the Examiner, claims 1-20 are allegedly not commensurate with the enabling disclosure to a skilled artisan. Applicant respectfully traverses the rejection.

One of skill in the art of the invention would be able to practice the subject invention without undue experimentation. For example, claim 1 is directed at "[a] method for delivering a molecule to a patient" and it further recites "administering amniotic epithelial cells to the skin of the patient; wherein said cells are capable of delivering said molecule." Thus, claim 1 describes a method and method steps. Applicant submits that a skilled artisan would be enabled to practice the method described in claim 1 without undue experimentation and that the skilled artisan could follow the steps recited in claim 1 without undue experimentation. Applicant does not fully appreciate the nexus of the Examiner's reasoning to the subject invention as recited and respectfully submits that the subject claims are fully enabled.

Applicant therefore respectfully requests withdrawal of this rejection.

V. 35 U.S.C. §102

a. Claims 1-12 and 14-20 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by United States Patent No. 6,117,676 to Sakuragawa (“Sakuragawa”), and the Examiner alleges that such anticipation is evidenced by Uchida *et al.*, 2000, J. Neurosci. Res. 62:585-590 (“Uchida”). Applicant respectfully traverses the rejection.

Sakuragawa does not teach or suggest “delivering a molecule to a patient” by “administering amniotic epithelial cells to the skin” so that a molecule is delivered to the patient, as described in the claims. Sakuragawa discusses gene therapy that involves the transplantation of “amniotic cells” into the patient (e.g., column 3, lines 51-59) and that the cells are transplanted “subcutaneously” (e.g., column 4, lines 2-3). Sakuragawa can therefore not anticipate (or obviate) the subject invention as it does not teach or suggest each and every element described in the claims (for example, “administering amniotic epithelial cells to the skin”). Applicant submits that Uchida does not cure the deficiencies of Sakuragawa and the Examiner has not shown otherwise.

Applicant therefore respectfully requests withdrawal of this rejection.

b. Claims 1-5, 7-13, 16-18 and 20 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Faulk *et al.*, 1980, Lancet 1(8179):1156-1158 (“Faulk”), and the Examiner alleges that such anticipation is evidenced by Uchida. Applicant respectfully traverses the rejection.

Applicant respectfully submits that Faulk does not teach or suggest, at least, “delivering a molecule to a patient” by “administering amniotic epithelial cells to the skin of the patient” and “wherein said cells are capable of delivering said molecule.” The Examiner alleges that “[i]nasmuch as the cells of Faulk are composed of molecules, Faulk teaches the delivery of molecules to a patient.” Yet, the cells described in the subject claims “are capable of delivering said molecule,” which is inconsistent with the Examiner’s allegation. Applicant submits that Uchida does not cure the deficiencies of Sakuragawa and the Examiner has not shown otherwise.

Applicant therefore respectfully requests withdrawal of this rejection.

c. Claims 16-19 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Eming *et al.*, 1996, Biotech. Bioeng. 52(1):15-23 ("Eming"). Applicant respectfully traverses the rejection.

Applicant respectfully submits that Eming discusses the use of cells "inserted under a full-thickness skin flap" (page 17, left column). Eming does not discuss "delivering a molecule to a patient" in "a nutrient-poor environment found on the skin" as described in the subject claims.

Applicant therefore respectfully requests withdrawal of this rejection.

VI. 35 U.S.C. §103

a. Claims 1-6 and 14-19 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Faulk in view of Eming and Sakuragawa. Applicant respectfully traverses the rejection.

Applicant discussed above the deficiencies of the primary reference Faulk cited by the Examiner, and Applicant also discussed the deficiencies of Eming and Sakuragawa, and Eming and Sakuragawa therefore do not cure the deficiencies of Faulk.

Applicant also notes that no suggestion to combine Faulk, Eming and Sakuragawa has been shown and Applicant respectfully requests that the requisite evidence for a suggestion to combine these references be made of record. ("When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. ... 'The factual inquiry whether to combine references must be thorough and searching.' ... It must be based on objective evidence of record." *In re Sang-Su Lee*, 277 F.3d 1338, 1343, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002)(citations omitted).)

Applicant therefore respectfully requests withdrawal of this rejection.

b. Claims 1-6 and 14-19 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Faulk in view of Eming, Sakuragawa and United States Patent Number 6,191,269 to Pollock *et al.* ("Pollock"). Applicant respectfully traverses the rejection.

Applicant discussed above the deficiencies of Faulk, Eming and Sakuragawa, and Pollock does not cure the deficiencies of these references and the Examiner does not allege otherwise. Also, no evidence of any suggestion to combine any or all of these references has been made of record and Applicant respectfully requests same.

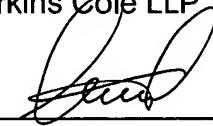
Applicant therefore respectfully requests withdrawal of this rejection.

VII. Conclusion

Applicant respectfully submits that pending claims 1-20 are in condition for immediate allowance. The undersigned invites the Examiner to call (650) 838-4382 with any questions or comments. The Commissioner is hereby authorized and requested to charge any deficiency in fees herein to Deposit Account No. 50-2207.

Respectfully submitted,
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Date: November 22, 2004



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